Appl. No.: 10/618,223
Amdt. dated 08/03/2005
Reply to Office action of February 17, 2005

Amendments to the Specification:

1. Please amend page 6, line 16 as follows:

FIG. 22 is a side view of the measuring portion of the lumen-measuring device of FIG. 19, showing the measurement markers on the dilation balloon in the uninflated configuration;

2. Please amend page 6, line 29 as follows:

FIG. 26 is a side view of the measuring portion of the lumen-measuring device of FIG. 19, showing the measurement markers on the dilation and diameter measurement balloons in the inflated configuration;

3. Please amend page 9, line 7 as follows:

In a preferred embodiment, the lumen-measuring device 100 comprises a plurality of conduits longitudinally extending between proximal and distal ends, namely exterior 130 and interior 180 conduits, the exterior conduit 130 is coupled with a handle 220 at the proximal end and a measurement assembly 240 at the distal end. The handle 220 and the measurement assembly 240 being operatively connected with one another via the interior conduit 180 at the interior conduit's proximal 190 and distal ends 200, respectively. The interior conduit 180 also has a depth marking mechanism 210 visible through the proximal region of the exterior conduit 140. The handle 220 provides a trigger mechanism 230 that allows the user to place the measurement assembly 240 in an open or closed configuration by pushing or pulling the trigger mechanism 230. The trigger 230 is preferably a slide-gauged mechanism but may be any number of alternative guiding systems known in the art. In the slide gauge embodiment, when the trigger mechanism 230 is pushed in a distal direction with respect to the handle 220, the interior conduit 180 urges the measurement assembly 240 distal the exterior conduit 130 causing the measurement assembly 240 to open. Retracting the trigger mechanism 230 in a proximal direction with respect to the handle 220 closes the measurement assembly ~~230~~240.

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4. Please amend page 9, line 13 as follows:

The measurement assembly 230 comprises at least two legs 250, 300 having distal 260, 310 and proximal ends 270, 320 and inward facing 280, 330 and lumen facing 290, 340 surfaces, the legs are preferably coupled with each other at their respective proximal ends 270, 320. Distal the point at which the legs 250, 300 are coupled, the legs 250, 300 are designed to diverge 410 from one another when unconstrained. In the furtherance of this objective, the legs 250, 300 are preferably formed of a shape memory alloy such as nitinol so that when the legs are constrained by the exterior conduit 130 they lay substantially flush with respect to one another but diverge when the exterior conduit 130 is evacuated.

5. Please amend page 10, line 18 as follows:

Referring now to FIGS. 14-18, in an alternative embodiment, instead of the distal ends of the legs making independent contact with the lumen surface, the distal ends are coupled together with a coupler 400 so that measurement takes place proximal the distal ends of the legs. In this embodiment, the measurement assembly takes on the configuration of a whisk, wherein the exterior diameter at the distal and proximal ends, when if fully extended, is significantly smaller relative to the measurement portion there between. However, when the measurement assembly is retracted, the legs are relaxed and reside adjacent one another so that the legs may be retracted within the exterior conduit.

6. Please amend page 10, line 29 and page 11, line 5 as follows:

In this and other related embodiments, the exterior conduit has measurement markers 160 formed thereon. Additionally, the lumen facing surfaces ~~280~~290, ~~330~~340 of the measurement assembly 240 legs have measurement markers 350 and/or 360 formed thereon. As the trigger mechanism 230 is pushed distally, the measurement assembly 240 moves distal the distal end 150 of the exterior conduit 130 and begins to separate the legs of the measurement assembly 240 with respect to one another. The further the trigger mechanism[[s]] 230 is pushed in the distal directions, the further the legs open and the greater the number of measurement markings 350 and/or 360 on the measurement assembly 240 extended beyond the distal end of 150 of the

exterior conduit 130. In a preferred embodiment, the distal end 150 of the exterior conduit 130 have inward facing detents or lip 170 that are complementary to the measurement markers 350 and/or 360 on the measurement assembly 240. At each measurement marking 350, the detent lip 170 may be engaged by the detent catches 360 of the measurement marker 350 to prevent overshooting the target. Once the legs have been opened until the distal ends of the legs of the measurement assembly 240 are in contact with the tissue to be measured, the user need only count the measurement markings 350 to determine the desired dimensions of the target tissue.

7. Please amend pages 11, line 29 and page 12, line 2 as follows:

An alternative embodiment of the present invention, as shown specifically in FIGS. 19-30 comprises a flexible device 420 with preferably two balloons and three conduits--one conduit for each balloon and one that goes all the way through. The bottom balloon is substantially flat and round and is referred to generally as the diameter measurement balloon ~~480~~470; the upper balloon is longer and narrow and is referred to generally as the dilation balloon 430. The first conduit 520 preferably inflates the ~~diameter measurement~~ diameter measurement balloon 470 and the second conduit 550 inflates the dilation balloon 430. The third conduit 560, which preferably terminates at the distal end tip 540, principally serves a delivery and measurement function. In a preferred embodiment, the outermost conduit 520 has measurement markings 530 that are visible from the interior and/or the exterior thereof.

8. Please amend page 13, line 2 as follows:

Through the use of visualization means, such as optical instruments like an end 120 of a bronchoscope 110, the topology of the stenosis 580 can be directly viewed. The diameter measurement balloon 470 is preferably designed with diameter measurement markers 510 formed on the proximal face thereof to allow the user to visually measure the extent of luminal occlusion based on the number of diameter measurement markers covered by the stenosis 580 when viewing the diameter measurement balloon 470 from a position proximal the stenosis 580. Furthermore, this allows the physician to see if the stenosis 580, or other observed occlusion, is symmetrical, etc.